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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1753	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,262	BLACK ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 34-43* is/are rejected.

7)☒ Claim(s) *30-33* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/10/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: IDS of 6/27/2005, IDS of 01/21/2005,IDS of 12/06/2004, IDS of 10/04/2004, IDS of 07/28/2004, IDS of 12/22/2003, IDS of 10/31/2003, and IDS of 09/17/2003.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4, 7-9, 13, 17-20, 25, and 26 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Chan (US 6,627,058 B1).

Addressing claims 1 and 13, Chan discloses a non-mediated enzyme electrode for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme and of an electric potential on the electrode (col. 03:01-10), the electrode comprising a base substrate on which is provided

(a) an electrically conductive base layer comprising finely divided platinum group

metal bonded together by a resin (claim 1; col. 09:50-60; col. 04:3-38; and col. 06:45 – col. 07:19);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:25-31); and

(c) a catalytically active quantity of the oxidoreductase enzyme in the top layer (col. 08:25-31).

Addressing claims 2, 7, and 18, for the additional limitations of these claims see col. 08:25-31.

Addressing claims 3, 4, 19, and 20 , for the additional limitations of these claims see col. 08:25-29 and col. 08:6-8.

Addressing claims 8, 9, 25, and 26, for the additional limitations of these claims see claim 1; col. 09:50-60; and col. 04:3-38.

Addressing claim 17, Chan discloses a non-mediated biosensor for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme, the biosensor comprising

(a) a base substrate (col. 07:58-59);

(b) a working electrode (col. 07:50-52) and a reference electrode (col. 07:50-53) on the base substrate (col. 07:50-59);

(c) conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus (col. 07:60-62);

wherein the working electrode includes

(d) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (claim 1; col. 09:50-60; col. 04:3-38; and col. 06:45 – col. 07:19);

(e) a top layer on the base layer, the top layer comprising a buffer (col. 08:25-31); and

(f) a catalytically active quantity of the oxidoreductase enzyme in the top layer (col. 08:25-31).

3. Claims 1-4 and 8-14 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Asakura et al. (EP 0771867 A2) ("Asakura").

Addressing claims 1 and 13, Asakura discloses a non-mediated enzyme electrode for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme

and of an electric potential on the electrode (col. 01:01-09), the electrode comprising a base substrate on which is provided

(a) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (col. 07:34 – col. 08:30);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:45-55); and

(c) a catalytically active quantity of the oxidoreductase enzyme in the top layer (col. 08:45-55).

Addressing claims 2-4, for the additional limitations of these claim see col. 08:45-50. For claims 3 and 4 note that the buffer is used "to effect neutralization."

Addressing claims 8 and 9, for the additional limitations of these claims see col. 07:34 – col. 08:30.

Addressing claims 10-12 and 9, for the additional limitations of these claims see col. 07:34 – col. 08:30, especially col. 08:05-15, which discloses mixing bovine serum albumin with the finely divided particles.

Addressing claim 14, for the additional limitations of these claims see col. 08:19-21.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 5, 6, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 6,627,058 B1) in view of Yugawa et al. (US 6,656,702 B1) ("Yugawa") and Karinka et al. (US 6,863,800 B2) ("Karinka").

Addressing claims 5 and 6, Chan discloses a non-mediated enzyme electrode for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme and of an electric potential on the electrode (col. 03:01-10), the electrode comprising a base substrate on which is provided

(a) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (claim 1; col. 09:50-60; col. 04:3-38; and col. 06:45 – col. 07:19);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:25-31); and

(c) a catalytically active quantity of the oxidoreductase enzyme in at least one of the top layer (col. 08:25-31).

Chan does not mention providing a polyol, such as trehalose, as a system stabiliser in the top layer.

Karinka and Yugawa disclose using polyol, such as trehalose, as a protein or enzyme stabilizer in an enzyme-based reagent layer for electrochemical biosensors.

See in Karinka Tables 1 and 2 (in column 14) and in Yugawa col. 02:03-12. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a polyol, such as trehalose, as a system stabilizer in the enzyme reagent layer as taught by Karinka and Yugawa in the invention of Chan because as taught by Yugawa it will protect "... the enzyme from any environmental changes such as temperature, humidity and so on and secures stability of the enzyme activity for a long time." See col. 02:45-53.

Addressing claim 21 and 22, Chan discloses a non-mediated biosensor for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme, the biosensor comprising

(a) a base substrate (col. 07:58-59);

(b) a working electrode (col. 07:50-52) and a reference electrode (col. 07:50-53) on the base substrate (col. 07:50-59);

(c) conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus (col. 07:60-62);

wherein the working electrode includes

(d) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (claim 1; col. 09:50-60; col. 04:3-38; and col. 06:45 – col. 07:19);

(e) a top layer on the base layer, the top layer comprising a buffer (col. 08:25-31); and

(f) a catalytically active quantity of the oxidoreductase enzyme in the top layer (col. 08:25-31).

Chan does not mention providing a polyol, such as trehalose, as a system stabilizer in the top layer.

Karinka and Yugawa disclose using polyol, such as trehalose, as a protein or enzyme stabilizer in an enzyme-based reagent layer for electrochemical biosensors. See in Karinka Tables 1 and 2 (in column 14) and in Yugawa col. 02:03-12. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a polyol, such as trehalose, as a system stabilizer in the enzyme reagent layer as taught by Karinka and Yugawa in the invention of Chan because as taught by Yugawa it will protect "... the enzyme from any environmental changes such as temperature, humidity and so on and secures stability of the enzyme activity for a long time." See col. 02:45-53.

8. Claims 15, 16, 23, 24, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 6,627,058 B1).

Addressing claims 15 and 16, Chan discloses a non-mediated enzyme electrode for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme and of an electric potential on the electrode (col. 03:01-10), the electrode comprising a base substrate on which is provided

(a) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (claim 1; col. 09:50-60; col. 04:3-38; and col. 06:45 – col. 07:19);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:25-31); and

(c) a catalytically active quantity of the oxidoreductase enzyme in at least one of the top layer (col. 08:25-31).

Chan does not mention having the ratio of buffer to enzyme be in one of the claimed ranges; however, barring evidence to the contrary, such as unexpected results, the relative amount of enzyme to buffer provided in the enzyme electrode is just a matter of optimizing the enzyme electrode for the sensitivity of the enzyme to pH change and the buffering capacity of the buffer to be used.

Addressing claims 23 and 24, Chan discloses a non-mediated biosensor for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme, the biosensor comprising

(a) a base substrate (col. 07:58-59);

(b) a working electrode (col. 07:50-52) and a reference electrode (col. 07:50-53) on the base substrate (col. 07:50-59);

(c) conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus (col. 07:60-62);

wherein the working electrode includes

(d) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (claim 1; col. 09:50-60; col. 04:3-38; and col. 06:45 – col. 07:19);

(e) a top layer on the base layer, the top layer comprising a buffer (col. 08:25-31); and

(f) a catalytically active quantity of the oxidoreductase enzyme in the top layer (col. 08:25-31).

Chan does not mention having the ratio of buffer to enzyme be in one of the claimed ranges; however, barring evidence to the contrary, such as unexpected results, the relative amount of enzyme to buffer provided in the enzyme electrode is just a matter of optimizing the enzyme electrode for the sensitivity of the enzyme to pH change and the buffering capacity of the buffer to be used.

Addressing claim 41, Chan discloses a non-mediated enzyme electrode for indicating amperometrically the catalytic activity of an glucose oxidase in the presence of a fluid containing a substance acted upon by the enzyme and of an electric potential on the electrode (col. 03:01-10), the electrode comprising a base substrate on which is provided

(a) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (claim 1; col. 09:50-60; col. 04:3-38; and col. 06:45 – col. 07:19);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:25-31); and

(c) a catalytically active quantity of the oxidoreductase enzyme in the top layer (col. 08:25-31).

Chan does not state that the enzyme electrode is for indicating the catalytic activity of glucose oxidase in the presence of glucose in whole blood; the enzyme electrode is only tested with a prepared glucose solution. See col. 08:25-36. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to use the enzyme electrode on a whole blood sample because (1) Chan states that the invention addresses "a need for electrochemical sensor materials with much improved sensor performance of high catalytic activity/current response and low background noise to expand the capability of H_2O_2 – based biosensors for monitoring

biological analytes at the micromolar (μM) level and to assure a high confidence of detecting low level of analytes in body fluid" (col. 02:7-13), (2) the following embodiment is used to measure glucose in whole blood (col. 08:47-53), and (3) millions of glucose measurements are made on blood every day, perhaps it is the most common sample type in which glucose is measured.

Addressing claim 42, Chan discloses a non-mediated biosensor for indicating amperometrically the catalytic activity of glucose oxidase in the presence of a fluid containing a substance acted upon by the enzyme (03:01-10), the biosensor comprising

(a) a base substrate (col. 07:58-59);

(b) a working electrode (col. 07:50-52) and a reference electrode (col. 07:50-53) on the base substrate (col. 07:50-59);

(c) conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus (col. 07:60-62);

wherein the working electrode includes

(d) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (claim 1; col. 09:50-60; col. 04:3-38; and col. 06:45 – col. 07:19);

(e) a top layer on the base layer, the top layer comprising a buffer (col. 08:25-31); and

(f) a catalytically active quantity of the oxidoreductase enzyme in the top layer (col. 08:25-31).

Chan does not state that the enzyme electrode is for indicating the catalytic activity of glucose oxidase in the presence of glucose in whole blood; the enzyme electrode is only tested with a prepared glucose solution. See col. 08:25-36. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to use the enzyme electrode on a whole blood sample because (1) Chan states that the invention addresses "a need for electrochemical sensor materials with much improved sensor performance of high catalytic activity/current response and low background noise to expand the capability of H_2O_2 – based biosensors for monitoring biological analytes at the micromolar (μM) level and to assure a high confidence of detecting low level of analytes in body fluid" (col. 02:7-13), (2) the following embodiment is used to measure glucose in whole blood (col. 08:47-53), and (3) millions of glucose measurements are made on blood every day, perhaps it is the most common sample type in which glucose is measured.

9. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asakura et al. (EP 0771867 A2) ("Asakura") in view of Yugawa et al. (US 6,656,702 B1) ("Yugawa") and Karinka et al. (US 6,863,800 B2) ("Karinka").

Addressing claims 5 and 6, Asakura discloses a non-mediated enzyme electrode for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme and of an electric potential on the electrode (col. 01:01-09), the electrode comprising a base substrate on which is provided

(a) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (col. 07:34 – col. 08:30);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:45-55); and

(c) a catalytically active quantity of the oxidoreductase enzyme in at least one of the top layer (col. 08:45-55).

Asakura does not mention providing a polyol, such as trehalose, as a system stabilizer in the top layer.

Karinka and Yugawa disclose using polyol, such as trehalose, as a protein or enzyme stabilizer in an enzyme-based reagent layer for electrochemical biosensors. See in Karinka Tables 1 and 2 (in column 14) and in Yugawa col. 02:03-12. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a polyol, such as trehalose, as a system stabilizer in the enzyme reagent layer as taught by Karinka and Yugawa in the invention of Asakura because as taught by

Yugawa it will protect "... the enzyme from any environmental changes such as temperature, humidity and so on and secures stability of the enzyme activity for a long time." See col. 02:45-53.

10. Claims 7, 15, 16, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asakura et al. (EP 0771867 A2) ("Asakura").

Addressing claim 7, Asakura discloses a non-mediated enzyme electrode for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme and of an electric potential on the electrode (col. 01:01-09), the electrode comprising a base substrate on which is provided

(a) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (col. 07:34 – col. 08:30);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:45-55); and

(c) a catalytically active quantity of the oxidoreductase enzyme in at least one of the top layer (col. 08:45-55).

In the example relied upon to meet the claim limitations the enzyme is lactate oxidase. However, Asakura clearly contemplates that a variety of other enzymes, such as glucose oxidase, could be used. See col. 07:5-13. Barring evidence to the contrary,

such as unexpected results, the choice of enzyme will just depend on the analyte of interest.

Addressing claims 15 and 16, Asakura discloses a non-mediated enzyme electrode for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme and of an electric potential on the electrode (col. 01:01-09), the electrode comprising a base substrate on which is provided

(a) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (col. 07:34 – col. 08:30);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:45-55); and

(c) a catalytically active quantity of the oxidoreductase enzyme in at least one of the top layer (col. 08:45-55).

Asakura does not mention having the ratio of buffer to enzyme be in one of the claimed ranges; however, barring evidence to the contrary, such as unexpected results, the relative amount of enzyme to buffer provided in the enzyme electrode is just a matter of optimizing the enzyme electrode for the sensitivity of the enzyme to pH change and the buffering capacity of the buffer to be used.

Addressing claim 41, Asakura discloses a non-mediated enzyme electrode for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme and of an electric potential on the electrode (col. 01:01-09), the electrode comprising a base substrate on which is provided

(a) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (col. 07:34 – col. 08:30);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:45-55); and

(c) a catalytically active quantity of the oxidoreductase enzyme in the top layer (col. 08:45-55).

Asakura does not state that the enzyme electrode is for indicating the catalytic activity of glucose oxidase in the presence of glucose in whole blood; the enzyme electrode of the embodiment relied on to meet the other claim limitations is a lactate biosensor. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to use the enzyme electrode on a whole blood sample because (1) Asakura discloses that a variety of enzymes including glucose oxidase can be used so that different analytes may be measured including glucose (col. 05:39-41 and col. 07:05-10), and (2) since the claimed invention is structurally the same as the enzyme electrode disclosed by Asakura they should both have the same capabilities, namely the ability to indicate the catalytic activity of glucose oxidase in the presence of glucose in whole blood.

11. Claims 17-20, 25-28, 34-40, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asakura et al. (EP 0771867 A2) ("Asakura") in view of Ikeda et al. (US 5,575,895) ("Ikeda").

Addressing claim 17, Asakura discloses a non-mediated biosensor for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme (col. 01:01-09), the biosensor comprising a working electrode that includes

(a) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (col. 07:34 – col. 08:30);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:45-55); and

(c) a catalytically active quantity of the oxidoreductase enzyme in at least one of the top layer (col. 08:45-55).

Asakura does not mention providing a base substrate; a working

electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus.

Ikeda discloses a biosensor comprising a base substrate; a working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus. See the abstract and Figures 1 and 2.

It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a base substrate; the working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus as taught by Ikeda in the invention of Asakura because as taught by Ikeda "... substantially the whole of various components contained in the reaction layer can participate in the reaction. Therefore, the response of the sensor and its reproducibility can remarkably be improved." See col. 03:16-23.

Addressing claims 18-20 and 40, for the additional limitations of these claim see in Asakura col. 08:45-50. For claims 19 and 20 note that the buffer is used "to effect neutralization."

Addressing claims 23 and 24, Asakura does not mention having the ratio of buffer to enzyme be in one of the claimed ranges; however, barring evidence to the contrary, such as unexpected results, the relative amount of enzyme to buffer provided in the enzyme electrode is just a matter of optimizing the enzyme electrode for the sensitivity of the enzyme to pH change and the buffering capacity of the buffer to be used.

Addressing claims 25, 26, and 39, for the additional limitations of these claims see col. 07:34 – col. 08:30.

Addressing claim 27, Asakura discloses a method of manufacturing a non-mediated biosensor for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme (col. 01:01-09), the method comprising

(a) printing an ink containing finely divided platinum group metal and a resin binder (col. 07:34 – col. 08:30);

(b) causing or permitting the printed ink to dry to form an electrically conductive base layer comprising the platinum group metal bonded together by the resin (implied by col. 08:27-29) and

(c) forming a top layer on the base layer by coating the base layer with a coating medium comprising or containing a buffer (col. 08:45-48); wherein

(d) a catalytically active quantity of the oxidoreductase enzyme is provided in at the coating medium (col. 08:45-48).

Asakura does not mention providing a base substrate; a working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus.

Ikeda discloses a biosensor comprising a base substrate; a working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus. See the abstract and Figures 1 and 2.

It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a base substrate; the working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus as taught by Ikeda in the invention of Asakura (that is print the ink and coating medium onto the base substrate of Ikeda) because as taught by Ikeda "... substantially the whole of various components contained in the reaction layer can participate in the reaction. Therefore, the response of the sensor and its reproducibility can remarkably be improved." See col. 03:16-23.

Addressing claim 28, for the additional limitation of this claim see in Asakura col. 08:45-55.

Addressing claims 35-37, Asakura does not mention having the buffer concentration be in the claimed range or having the ratio of buffer to enzyme be in one of the claimed ranges; however, barring evidence to the contrary, such as unexpected results, the amount of buffer or relative amount of enzyme to buffer provided in the enzyme electrode is just a matter of optimizing the enzyme electrode for the sensitivity of the enzyme to pH change and the buffering capacity of the buffer to be used.

Addressing claims 34 and 38, for the additional limitations of these claims see col. 08:45-48.

Addressing claim 42, Asakura discloses a non-mediated biosensor for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme (col. 01:01-09), the biosensor comprising a working electrode that includes

(a) an electrically conductive base layer comprising finely divided platinum group metal bonded together by a resin (col. 07:34 – col. 08:30);

(b) a top layer on the base layer, the top layer comprising a buffer (col. 08:45-55); and

(c) a catalytically active quantity of the oxidoreductase enzyme in at least one of the top layer (col. 08:45-55).

Asakura does not mention providing a base substrate; a working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus.

Ikeda discloses a biosensor comprising a base substrate; a working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus. See the abstract and Figures 1 and 2.

It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a base substrate; the working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus as taught by Ikeda in the invention of Asakura because as taught by Ikeda "... substantially the whole of various components contained in the reaction layer can participate in the reaction. Therefore, the response of the sensor and its reproducibility can remarkably be improved." See col. 03:16-23.

Asakura does not state that the enzyme electrode is for indicating the catalytic activity of glucose oxidase in the presence of glucose in whole blood; the enzyme electrode of the embodiment relied on to meet the other claim limitations is a lactate

biosensor. However, it would have been obvious to one with ordinary skill in the art at the time of the invention to use the enzyme electrode on a whole blood sample because (1) Asakura discloses that a variety of enzymes including glucose oxidase can be used so that different analytes may be measured including glucose (col. 05:39-41 and col. 07:05-10), and (2) since the claimed invention is structurally the same as the enzyme electrode disclosed by Asakura they should both have the same capabilities, namely the ability to indicate the catalytic activity of glucose oxidase in the presence of glucose in whole blood.

Addressing claim 43, Asakura discloses a method of manufacturing a non-mediated biosensor for indicating amperometrically the catalytic activity of an oxidoreductase enzyme in the presence of a fluid containing a substance acted upon by the enzyme (col. 01:01-09), the method comprising

(a) printing an ink containing finely divided platinum group metal and a resin binder (col. 07:34 – col. 08:30);

(b) causing or permitting the printed ink to dry to form an electrically conductive base layer comprising the platinum group metal bonded together by the resin (implied by col. 08:27-29) and

(c) forming a top layer on the base layer by coating the base layer with a coating medium comprising or containing a buffer (col. 08:45-48); wherein

(d) a catalytically active quantity of the oxidoreductase enzyme is provided in at the coating medium (col. 08:45-48).

Asakura does not mention providing a base substrate; a working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus.

Ikeda discloses a biosensor comprising a base substrate; a working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus. See the abstract and Figures 1 and 2.

It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a base substrate; the working electrode and a reference electrode on the base substrate; and conductive tracks connected to the electrodes for making electrical connections with a test meter apparatus as taught by Ikeda in the invention of Asakura (that is print the ink and coating medium onto the base substrate of Ikeda) because as taught by Ikeda "... substantially the whole of various components contained in the reaction layer can participate in the reaction. Therefore, the response of the sensor and its reproducibility can remarkably be improved." See col. 03:16-23.

Asakura does not state that the enzyme electrode is for indicating the catalytic activity of glucose oxidase in the presence of glucose in whole blood; the enzyme electrode of the embodiment relied on to meet the other claim limitations is a lactate biosensor. However, it would have been obvious to one with ordinary skill in the art at

the time of the invention to use the enzyme electrode on a whole blood sample because (1) Asakura discloses that a variety of enzymes including glucose oxidase can be used so that different analytes may be measured including glucose (col. 05:39-41 and col. 07:05-10), and (2) since the claimed invention is structurally the same as the enzyme electrode disclosed by Asakura they should both have the same capabilities, namely the ability to indicate the catalytic activity of glucose oxidase in the presence of glucose in whole blood.

12. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asakura et al. (EP 0771867 A2) ("Asakura") in view of Ikeda et al. (US 5,575,895) ("Ikeda") as applied to claims 17-20, 25-28, 34-38 above, and further in view of Yugawa et al. (US 6,656,702 B1) ("Yugawa") and Karinka et al. (US 6,863,800 B2) ("Karinka").

Asakura as modified by Ikeda does not mention providing a polyol, such as trehalose, as a system stabilizer in the top layer.

Karinka and Yugawa disclose using polyol, such as trehalose, as a protein or enzyme stabilizer in an enzyme-based reagent layer for electrochemical biosensors. See in Karinka Tables 1 and 2 (in column 14) and in Yugawa col. 02:03-12. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a polyol, such as trehalose, as a system stabilizer in the enzyme reagent layer

as taught by Karinka and Yugawa in the invention of Asakura as modified by Ikeda because as taught by Yugawa it will protect "... the enzyme from any environmental changes such as temperature, humidity and so on and secures stability of the enzyme activity for a long time." See col. 02:45-53.

13. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Asakura et al. (EP 0771867 A2) ("Asakura") in view of Ikeda et al. (US 5,575,895) ("Ikeda") as applied to claims 17-20, 25-28 above, and further in view of Karinka et al. (US 6,863,800 B20 ("Karinka") and Henning et al. (US 6,565,738 B1) ("Henning") .

Asakura as modified by Ikeda do not mention applying the coating fluid by drop coating, only dispensing the coating fluid (Asakura col. 08:45-53). However, as shown by Henning and Karinka drop coating was one of several alternative ways known at the time of the invention. See in Henning col. 14:57-60 and in Karinka col. 07:55-65. Barring a contrary showing, such as unexpected results, selecting a coating method, such as drop coating, from known coating methods can just depend on available equipment and cost.

International Search Report for International Application No. PCT/GB03/02901

("Search Report")

14. US 5118404 A ("Saito") was cited as an "X" reference against claims 1, 17, and 27 in the Search Report. Claims 1 and 17 each require, among other things, "an electrically conductive base layer comprising finely divided platinum group metal or oxide bonded together by a resin." Claim 27 requires the step of "printing on the said working electrode an ink containing finely divided platinum group metal or oxide and a resin binder." In Saito the enzyme comprises an enzyme-immobilized membrane having pH capacity on an ion-sensitve field effect transistor (ISFET). See col. 04:23-28. The ISFET is not identified and Saito makes no mention of finely divided platinum group metal or oxide.

Allowable Subject Matter

15. Claims 30-33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

16. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 30: the combination of limitations requires the "the step of applying a spreading layer on the base layer prior to application of the coating fluid."

Asaruka adds the mixes the spreading composition with the ink containing the finely divided platinum group metal. See col. 08:16-21.

b) Claims 31-33 depend directly or indirectly from allowable claim 30.

Information Disclosure Statement ("IDS")

17. Applicants are requested to provide copies of the following references which are cited on the IDS of October 31, 2003, but have not been provided – B78 (JP2-62952), B79 (JP1-253648), and B80 (JP1-291153).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
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AU 1753
September 30, 2006